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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Thomas S.Y. KO et al

Appln. No.: 10/054,914

Filed: January 25, 2002



Conf. No.: 5596

Group Art Unit: 1619

Examiner: Unknown

For: METHOD OF PREPARING BIOLOGICAL MATERIALS
AND PREPARATIONS PRODUCED USING SAME

INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §§ 1.97 and 1.98

Commissioner for Patents
Washington, D.C. 20231

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicants hereby notify the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B (modified) (substitute for Form PTO-1449) form and/or listed herein and which the Examiner may deem material to patentability of the claims of the above-identified application.


A copy of each of the listed documents is submitted herewith.

The present Information Disclosure Statement is being filed after three months from the application's filing date for an application other than a Continued Prosecution Application (CPA) under §1.53(d), but before the mailing date of the first Office Action on the merits. Therefore, no Statement under 37 C.F.R. § 1.97(e) or fee under 37 C.F.R. § 1.17(p) is required.

INFORMATION DISCLOSURE STATEMENT
U.S. Appln. No. 10/054,914

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicants do not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

Respectfully submitted,



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Date: May 10, 2002

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INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

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Attorney Docket Number	Q-68257

Sheet 1 of 5

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Translation ⁶
		Country Code ³	Number ⁴	Kind Code ⁵ (if known)			
		AU	78721/87		03/24/1988	Enzacor Properties, Ltd.	
		AU	23673/92		02/23/1993	Enzacor Properties, Ltd.	

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.	Translation ⁶
		Cleland et al, <i>Pharm. Res.</i> , 13(10):1464-1475 (1996)	Abstract
		Cleland et al, <i>Pharm. Res.</i> , 14(4):420-425 (1997)	Abstract
		Yang et al, <i>J. Pharm. Sci.</i> , 86(8):908-914 (1986)	Abstract
		Johnson et al, <i>Pharm. Res.</i> , 14(6):730-735 (1997)	Abstract
		Jones et al, <i>Adv. Drug Deliv. Rev.</i> , 28(1):71-84 (1997)	Abstract
		Kim et al, <i>Biotechnol. Bioeng.</i> , 65(6):659-667 (1999)	Abstract
		Carrasquillo et al, <i>J. Pharm. Sci.</i> , 88(2):166-173 (1999)	Abstract
		Blanco et al, <i>Eur. J. Pharm. Biopharm.</i> , 45(3):285-294 (1998)	Abstract
		Costantino et al, <i>J. Pharm. Sci.</i> , 87(11):1412-1420 (1998)	Abstract
		Johnson et al, <i>Nat. Med.</i> , 2(7):795-799 (1996)	Abstract
		Brodbeck et al, <i>Pharm. Res.</i> , 16(12):1825-1829 (1999)	Abstract
		Sah et al, <i>PDA J. Pharm. Sci. Technol.</i> , 53(1):3-10 (1999)	Abstract
		Park et al, <i>J. Controlled Release</i> , 55(2-3):181-191 (1988)	Abstract
		Schwendeman et al, <i>J. Microencapsul.</i> , 15(3):299-318 (1998)	Abstract
		Gupta et al, <i>Vaccine</i> , 15(6-7):672-678 (1997)	Abstract
		Chang et al, <i>J. Pharm. Sci.</i> , 85(2):129-132 (1996)	Abstract
		Alonso et al, <i>Pharm. Res.</i> , 10(7):945-953 (1993)	Abstract
		Maa et al, <i>J. Pharm. Sci.</i> , 87(2):152-159 (1998)	Abstract
		Shenderova et al, <i>Pharm. Res.</i> , 14(10):1406-1414 (1997)	Abstract
		Uchida et al, <i>J. Microencapsul.</i> , 13(5):509-518 (1996)	Abstract
		Uchida et al, <i>Chem. Pharm. Bull.</i> , 44(1):235-236 (1996)	Abstract
		Lu et al, <i>PDA J. Pharm. Sci., Technol.</i> , 49(1):13-19 (1995)	Abstract
		Cohen et al, <i>Pharm. Res.</i> , 8(6):713-720 (1991)	Abstract
		Lam et al, <i>J. Controlled Release</i> , 67(2-3):281-292 (2000)	Abstract
		Jain et al, <i>J. Microencapsul.</i> , 17(3):343-362 (2000)	Abstract

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		Tracy, <i>Biotechnol. Prog.</i> , 14(1):108-115 (1998)	Abstract
		Tzannis et al, <i>J. Pharm. Sci.</i> , 88(3):351-359 (1999)	Abstract
		Katakam et al, <i>Pharm. Dev. Technol.</i> , 2(2):143-149 (1997)	Abstract
		Schwendeman et al, <i>Dev. Biol. Stand.</i> , 87:293-306 (1996)	Abstract
		Cleland, <i>Pharm. Biotechnol.</i> , 10:1-43 (1997)	Abstract
		Okada et al, <i>Crit. Rev. Ther. Drug Carrier Syst.</i> , 12(1):1-99 (1995)	Abstract
		Alonso et al, <i>Vaccine</i> , 12(4):299-306 (1994)	Abstract
		Leo et al, <i>J. Microcapsul.</i> , 15(4):421-430 (1998)	Abstract
		Putney, <i>Curr. Opin. Chem. Biol.</i> , 2(4):548-552 (1998)	Abstract
		Lam et al, <i>Pharm. Res.</i> , 14(6):725-729 (1997)	Abstract
		Takada et al, <i>PDA J. Pharm. Sci. Technol.</i> , 49(4):180-184 (1995)	Abstract
		Sato et al, <i>Pharm. Res.</i> , 5(1):21-30 (1988)	Abstract
		Pikal et al, <i>Pharm. Res.</i> , 8(4):427-436 (1991)	Abstract
		Costantino et al, <i>J. Pharm. Sci.</i> , 87(11):1406-1411 (1988)	Abstract
		Torres et al, <i>J. Microcapsul.</i> , 13(1):41-51 (1996)	Abstract
		Prestrelski et al, <i>Arch Biochem. Biophys.</i> , 303(2):465-473 (1993)	Abstract
		Hellebust et al, <i>Biotechnol Appl. Biochem.</i> , 18(Pt 3):227-237 (1993)	Abstract
		Zhu et al, <i>Pharm. Res.</i> , 17(3):351-357 (2000)	Abstract
		Maa et al, <i>Pharm. Dev. Technol.</i> , 2(3):213-223 (1997)	Abstract
		Zhang et al, <i>Pharm. Res.</i> , 12(10):1447-1452 (1995)	Abstract
		Iwata et al, <i>Pharm. Res.</i> , 10(8):1219-1227 (1993)	Abstract
		Heya et al, <i>J. Pharm. Sci.</i> , 83(5):636-640 (1994)	Abstract
		Mumenthaler et al, <i>Pharm. Res.</i> , 11(1):12-20 (1994)	Abstract
		Maharaj et al, <i>J. Pharm. Res.</i> , 73(1):39-42 (1984)	Abstract
		Alex et al, <i>J. Microencapsul.</i> , 7(3):347-355 (1990)	Abstract

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		Kendrick et al, <i>Proc. Natl. Acad. Sci. USA</i> , 95(24):14142-14146 (1998)	Abstract
		Uchida et al, <i>J. Pharm. Pharmacol.</i> , 47(7):556-560 (1995)	Abstract
		Sanghvi et al, <i>J. Microencapsul.</i> , 10(2):181-194 (1993)	Abstract
		Arakawa et al, <i>Biopolymers</i> , 29(6-7):1065-1068 (1990)	Abstract
		Johansen et al, <i>Eur. J. Pharm. Biopharm.</i> , 47(3):193-201 (1999)	Abstract
		Pikal et al, <i>Dev. Biol. Stand.</i> , 74:21-37 (1992)	Abstract
		Tzannis et al, <i>J. Pharm. Sci.</i> , 88(3):360-370 (1999)	Abstract
		Uchida et al, <i>J. Microencapsul.</i> , 13(2):219-228 (1996)	Abstract
		Tabata et al, <i>Pharm. Res.</i> , 10(4):487-496 (1993)	Abstract
		Gander et al, <i>J. Microencapsul.</i> , 12(1):83-97 (1995)	Abstract
		Hora et al, <i>Pharm. Res.</i> , 7(11):1190-1194 (1990)	Abstract
		Oroszlan et al, <i>Anal. Chem.</i> , 64(14):1623-1631 (1992)	Abstract
		Green et al, <i>Toxicol. Lett.</i> , 64-65:Spec. No. 321-327 (1992)	Abstract
		Pavlu et al, <i>Bioseparation</i> , 3(5):257-265 (1992-1993)	Abstract
		Andya et al, <i>Pharm. Res.</i> , 16(3):350-358 (1999)	Abstract
		Hayes et al, <i>Biotechnol. Bioeng.</i> , 59(5):557-566 (1998)	Abstract
		Eyles et al, <i>J. Pharm. Pharmacol.</i> , 49(7):669-674 (1997)	Abstract
		Heelan et al, <i>J. Microencapsul.</i> , 14(1):63-78 (1997)	Abstract
		Di Silvio et al, <i>Biomaterials</i> , 15(11):931-936 (1994)	Abstract
		Arakawa et al, <i>Biochemistry</i> , 29(7):1914-1923 (1990)	Abstract
		Wan et al, <i>J. Microencapsul.</i> , 9(3):309-316 (1992)	Abstract
		Bam et al, <i>J. Pharm. Sci.</i> , 87(12):1554-1559 (1998)	Abstract
		Leuckel et al, <i>Pharm. Dev. Technol.</i> , 3(3):337-346 (1998)	Abstract
		Carpenter et al, <i>Arch Biochem. Biophys.</i> , 303(2):456-464 (1993)	Abstract
		Pongpaibul et al, <i>J. Pharm. Pharmacol.</i> , 40(8):530-533 (1988)	Abstract

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		Iwata et al, <i>J. Microencapsul.</i> , 9(2):201-214 (1992)	Abstract
		Vudathala et al, <i>Pharm. Res.</i> , 9(6):759-763 (1992)	Abstract
		Huatan et al, <i>J. Microencapsul.</i> , 12(5):557-567 (1995)	Abstract
		Chen et al, <i>J. Microencapsul.</i> , 11(4):395-407 (1994)	Abstract
		Uchida et al, <i>Biol. Pharm. Bull.</i> , 17(9):1272-1276 (1994)	Abstract
		Short et al, <i>Pharm. Res.</i> , 12(8):1140-1145 (1995)	Abstract
		Margalit et al, <i>J. Microencapsul.</i> , 2(3):183-196 (1985)	Abstract
		Jones et al, <i>J. Pharm. Pharmacol.</i> , 41(12):813-816 (1989)	Abstract
		Costantino et al, <i>Biotechnology</i> , 13(5):493-496 (1995)	Abstract
		Ma et al, <i>J. Drug Target</i> , 2(1):9-21 (1994)	Abstract
		Bindschaedler et al, <i>J. Pharm. Sci.</i> , 77(8):696-698 (1988)	Abstract
		Page et al, <i>J. Pharm. Pharmacol.</i> , 52(1):19-26 (2000)	Abstract
		Duddu et al, <i>Pharm. Res.</i> , 14(5):591-595 (1997)	Abstract
		Anchordoquy et al, <i>Arch. Biochem. Biophys.</i> , 332(2):231-238 (1996)	Abstract
		Sah et al, <i>Pharm. Res.</i> , 13(3):360-367 (1996)	Abstract
		Tsai et al, <i>Pharm. Res.</i> , 10(5):649-659 (1993)	Abstract
		Gekko et al, <i>Biochemistry</i> , 20(16):4667-4776 (1981)	Abstract
		Tabata et al, <i>Pharm. Res.</i> , 6(5):422-427 (1989)	Abstract
		Kita et al, <i>Drug. Des. Deliv.</i> , 6(3):157-167 (1990)	Abstract
		Hora et al, <i>Pharm. Res.</i> , 9(1):33-36 (1992)	Abstract
		Costantino et al, <i>J. Pharm. Sci.</i> , 86(12):1390-1393 (1997)	Abstract
		Cedrat et al, <i>Artif. Cells Blood Substit. Immobil. Biotechnol.</i> , 22(3):867-873 (1994)	Abstract
		Weiner et al, <i>Immunomethods</i> , 4(3):201-209 (1994)	Abstract
		Sah et al, <i>J. Microencapsul.</i> , 12(1):59-69 (1995)	Abstract
		Shukla et al, <i>Pharm. Res.</i> , 6(5):418-421 (1989)	Abstract

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